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WelchAllyn

12. Premarket Notification [510(k)] Summary

Submitted By: Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220
Phone: 315-554-5289
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Contact: Joshua S. Kim

Common Name: Electrocardiographs

Trade Name: CP 100 and CP 200 (including Spirometry)

Classification: 21 CFR 870.2340

Predicate Device: The legally marketed medical devices to which substantially equivalent to the following:

- PageWriter Trim Series Cardiograph (K031422)
- Spirometer System (Medikro D9 Spirometer) (K971336)

Description: The Welch Allyn Multi-Channel Electrocardiographs, the low cost CP 100 or full-featured CP200. Both feature full alphanumeric keyboards for easy and fast entry of patient demographics, user-programmable report formats printed on patient chart size thermal paper, ECG measurement, advanced filters for optimal ECG trace quality and battery or AC operation.

Intended Use:

The Welch Allyn Printing Electrocardiography and Spirometry Products (Subject Devices) are intended for use by trained operators in health facilities. The subject Devices will provide the following diagnostic functions:

- Acquiring, viewing, storing and printing ECG waveforms patients using ECG Front End modules and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional algorithms to generate measurements, data presentations, graphical presentations and interpretive statements on an advisory basis for patients of sixteen (16) years of age and above. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings.
- Using the optional Spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function including, but not limited to, maximal volume and flow of air that can be moved in and out of a patient's lungs. These measures are used in the diagnosis and monitoring of lung diseases and interventions for the treatment of certain lung diseases. The spirometer should only be used with patients able to understand the instructions for performing the test, such as with children greater than three (3) years of age.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Welch Allyn, Inc.
c/o Mr. Christopher Klaczyk
Regulatory Affairs Manager
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K050074
Trade Name: CP 100 and CP 200 (including Spirometry)
Regulation Number: 21 CFR 892.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 8, 2005
Received: March 9, 2005

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11. Statement of Indications For Use

510(k) Number (if known): **K050074**

Device Name: **CP100 and CP200**

Indications For Use:

The Welch Allyn Printing Electrocardiography and Spirometry Products (Subject Devices) are intended for use by trained operators in health facilities. The subject Devices will provide the following diagnostic functions:

- Acquiring, viewing, storing and printing ECG waveforms patients using ECG Front End modules and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional algorithms to generate measurements, data presentations, graphical presentations and interpretive statements on an advisory basis for patients of sixteen (16) years of age and above. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings.
- Using the optional Spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function including, but not limited to, maximal volume and flow of air that can be moved in and out of a patient's lungs. These measures are used in the diagnosis and monitoring of lung diseases and interventions for the treatment of certain lung diseases. The Spirometer may be used with patients that are able to understand the instructions for performing the test, however normal values and interpretive results are not calculated for children under the age of six.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) and/or Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050074